K012446

OCT - 3 2001

**Charles A. Smith**
**811 Starlite Drive**
**Louisville, KY 40207**

## Non-Confidential Summary of Safety and Effectiveness

July 2001

Charles A. Smith
811 Starlite Drive
Louisville, KY 40207

Tel - 502-969-9652 Fax - 502-969-9777

| | |
|---|---|
| **Official Contact:** | Charles A. Smith |
| **Proprietary or Trade Name:** | OBA-1™ MRI - Office Based Anesthesia Unit MRI |
| **Common/Usual Name:** | Anesthesia gas machine |
| **Classification Name:** | Gas machine, anesthesia |
| **Predicate Devices:** | Smith - OBA-1™ - K000859 |
| | Dräger - Narkomed MRI Anesthesia System K972848 |

### Device Description:

The OBA-1™ MRI is an anesthesia unit which includes these features:

- Can be connected to a central pipeline or cylinder oxygen/air source
- Oxygen flowmeter 0 - 10 L/min
- Air flowmeter 0 - 10 L/min
- Oxygen and air pipeline pressure gauges 0 - 100 psi
- Oxygen Supply Failure Alarm
- Vaporizer - temperature and pressure compensated
- Oxygen Flush valve
- Back Pressure Check valve
- Indexed Fresh Gas Common outlet with safety lock
- Patient Manifold with directional valves - inspiratory and expiratory
- Adjustable APL valve with 19 mm waste gas outlet connection which can be connected to an active scavenging system
- MRI compatible Airway Pressure Gauge
- Oxygen sensor port
- Circuit Pressure monitor and gauge connection ports

- THERM$H_2$OSORB – Sodalime CO2 absorber
- Bag/Ventilator Switch Valve - 22 mm breathing bag port and 22 mm ventilator hose port

| | |
|---|---|
| 1. Intended use - | The OBA-1™ MRI is intended to provide continuous gas inhalation for patient requiring anesthesia under the direct care and supervision of a trained and qualified practitioner. It provides for oxygen delivery with an anesthetic agent, via the specific vaporizer, of the practitioner's choice. The OBA-1™ MRI is intended for use in an MRI environment of 1.5 tesla or less. It is to be used with an oxygen monitor and other suitable monitors. |
| 2. Environment of Use - | Physician office; day surgery center; dental office; MRI environment |
| 3.Patient Population - | Patients requiring general anesthesia by inhalation |

## Comparison to Other Legally Marketed Predicate Devices

The following comparison table details the primary attributes of the intended device and legally marketed predicate devices. The most significant attributes have been listed.

A glossary of the predicate devices:

| Company | Model | 510(k) status |
|---|---|---|
| 1. Smith | OBA-1™ | K000859 |
| 2. Penlon | Sigma Elite Vaporizer | K942545 |
| 3. Clippard | Oxygen Flush valve | exempt |
| | One way check valve | exempt |
| 4. Anesthesia Associates | MRI Airway pressure gauge | preamendment |
| | Bag/Ventlator Switch Valve with APL Valve | preamendment |

| | | |
|---|---|---|
| | Oxygen sensor port | preamendment |
| 5. Smith | THERM$H_2$OSORB | exempt - K954280 |
| 6. Porter Instruments | Flowmeters | exempt |

| Attribute | Proposed device OBA-1 MRI | Predicate Devices are listed under each attribute |
|---|---|---|
| **Use** | | |
| Intended to provide anesthesia delivery in office or outpatient setting and MRI scanning rooms | Yes | 1 |
| **Design** | | |
| Can be connected to central pipeline systems or cylinder yokes with regulators | Yes | 1 |
| Two gas flowmeters; 1 (oxygen) 1 (air) | Yes | 1 |
| Utilizes standard flowmeters | Yes | 1, 6 |
| Utilizes a disposable $CO_2$ absorber canister | Yes | 1, 5 |
| Has directional valves (inspiratory/ expiratory) | Yes | 1 |
| Incorporates standard 510(k) cleared vaporizers | Yes | 1, 2 |
| Has an APL valve with gas scavenging | Yes | 1, 4 |
| Manual ventilation via a breathing bag or automatic ventilation with ventilator | Yes | 1 |
| Has oxygen monitoring port | Yes | 1 |
| Has patient pressure monitoring port | Yes | 1 |

| Attribute | Proposed device OBA-1 MRI | Predicate Devices are listed under each attribute |
|---|---|---|
| **Design (continued)** | | |
| Connects to standard anesthesia breathing circuits | Yes | 1, 5 |
| Has oxygen flush valve | Yes | 1, 3 |
| **Materials** | | |
| Materials are standard for use in anesthesia gas machines | Yes | 1, 2, 3, 4, 5, 6 |
| **Packaging** | | |
| Provided clean, non-sterile | Yes | 1, 5 |
| Can be cleaned and disinfected | Yes | 1, 4 |
| **Performance Standards / Specifications** | | |
| None applicable under Section 514 | Yes | 1, 2, 3, 4, 5, 6 |

**Differences Between Other Legally Marketed Predicate Devices**

There are no functional differences between the proposed device and the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

Mr. Charles A. Smith
811 Starlite Drive
Louisville, KY 40207

Re: K012446
OBA-A™ MRI Anesthesia Machine
Regulation Number: 868.5160
Regulation Name: Gas Machine For Anesthesia
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: September 11, 2001
Received: September 14, 2001

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

**510(k) Number:** K012446 (To be assigned)

**Device Name:** Office Based Anesthesia Machine - **OBA-1™ MRI**

**Intended Use :** The Office Based Anesthesia Unit - OBA-1™ MRI is intended for administration of general inhalation anesthesia using mixtures of oxygen, air and volatile anesthetics, and for providing breathing gas and for either spontaneous ventilation or controlled ventilation of patient lungs.

The OBA-1™ MRI can be used in MRI scanner rooms with shielded or unshielded magnets up to 1.5 tesla.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012446

**Prescription Use** ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)